

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows.

5 Claim 1 (withdrawn): A pharmaceutical formulation comprising one or
more excipients and 3 α ,16 α ,17 β -trihydroxy-5 α -androstane, 3 α ,16 α -
dihydroxy-17-oxo-5 α -androstane, 3 β ,16 α ,17 β -trihydroxy-5 α -androstane,
3 β ,16 α -dihydroxy-17-oxo-5 α -androstane, 3 α ,16 β ,17 β -trihydroxy-5 α -
androstane, 3 α ,16 β -dihydroxy-17-oxo-5 α -androstane, 3 β ,16 β -dihydroxy-17-
oxo-5 α -androstane, 3 α ,16 α ,17 β -trihydroxy-5 β -androstane, 3 α ,16 α -dihydroxy-
10 17-oxo-5 β -androstane, 3 β ,16 α ,17 β -trihydroxy-5 β -androstane, 3 β ,16 α -
dihydroxy-17-oxo-5 β -androstane, 3 α ,16 β ,17 β -trihydroxy-5 β -androstane,
3 α ,16 β -dihydroxy-17-oxo-5 β -androstane, 3 β ,16 β -dihydroxy-17-oxo-5 β -
androstane or a 2-oxa, 11-oxa or 19-nor analog of any of these compounds.

15 Claim 2 (withdrawn): The pharmaceutical formulation of claim 1
wherein the compound is 3 α ,16 α ,17 β -trihydroxy-5 α -androstane.

20 Claim 3 (withdrawn): The pharmaceutical formulation of claim 1
wherein the compound is 3 α ,16 α -dihydroxy-17-oxo-5 α -androstane.

25 Claim 4 (withdrawn): A pharmaceutical formulation for buccal or
sublingual administration comprising one or more excipients and a compound
wherein the compound is 16 α -fluoro-17-oxoandrost-5-ene, 3 α -hydroxy-16 α -
fluoro-17-oxoandrost-5-ene, 3 β -hydroxy-16 α -fluoro-17-oxoandrost-5-ene 7 α -
hydroxy-16 α -fluoro-17-oxoandrost-5-ene, 7 β -hydroxy-16 α -fluoro-17-
oxoandrost-5-ene, 16 α -fluoro-7,17-dioxoandrost-5-ene.

30 Claim 5 (withdrawn): The pharmaceutical formulation of claim 4
wherein the compound is micronized.

Claim 6 (withdrawn): The pharmaceutical formulation of claim 4 wherein the compound is 16 α -fluoro-17-oxoandrost-5-ene.

5 Claim 7 (withdrawn): A pharmaceutical formulation comprising one or more excipients and two or more of 3 β -hydroxy-16 α -bromo-17-oxo-5 α -androstane, 3 β -hydroxy-16 β -bromo-17-oxo-5 α -androstane and 3 β -hydroxy-16 α -bromo-17-oxo-5 α -androstane hemihydrate.

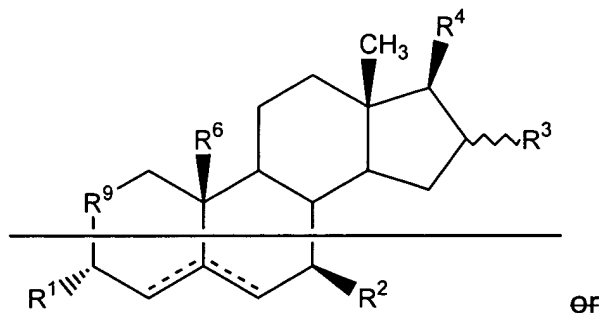
10 Claim 8 (withdrawn): The pharmaceutical formulation of claim 7 wherein the pharmaceutical formulation is for oral, buccal, sublingual or aerosol administration.

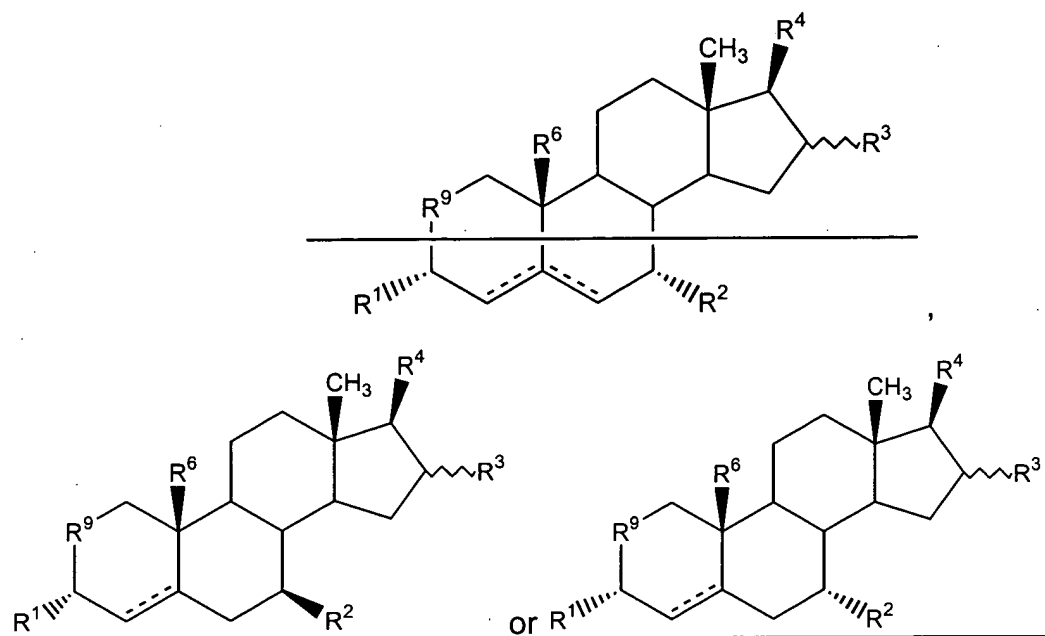
15 Claim 9 (original): The pharmaceutical formulation of claim 7 comprising 7 3 β -hydroxy-16 β -bromo-17-oxo-5 α -androstane and 3 β -hydroxy-16 α -bromo-17-oxo-5 α -androstane hemihydrate.

20 Claim 10 (withdrawn): The pharmaceutical formulation of claim 9 wherein the pharmaceutical formulation is for oral, buccal, sublingual or aerosol administration.

Claims 11-31 (canceled)

25 Claim 32 (currently amended): A method to treat osteoporosis or a bone fracture in a subject in need thereof, comprising administering to the subject an effective amount of a compound having the structure





wherein,

R¹ is -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, -N₃, -NO₂, an ester, a thioester, a phosphoester, a phosphothioester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, a carbonate, a carbamate, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

R² and R³ independently are -H, -OR^{PR}, =O, -SR^{PR}, =S, -N(R^{PR})₂, -N₃, =NOH, -CN, -NO₂, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, a substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group;

R⁴ is -OR^{PR}, =O, -SR^{PR}, =S, -N(R^{PR})₂, -N₃, =NOH, -NO₂, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

R⁶ is -H or optionally substituted alkyl;

R⁹ is -CHR¹⁰-, wherein R¹⁰ is -H, -OH, =O, -SH, halogen, an ester, a thioester, an amino acid, a peptide, an ether, a thioether, optionally

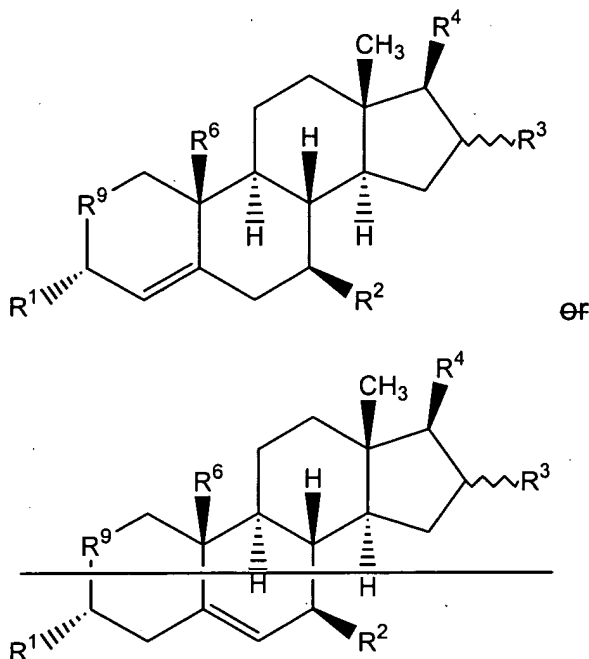
substituted alkyl, optionally substituted alkenyl or ~~optionally substituted~~
alkynyl; or optionally substituted alkynyl; and

R^{13} independently is C_{1-6} alkyl;

R^{PR} independently are -H or a protecting group.

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Claim 33 (currently amended): The method of claim 32 wherein the
subject has osteoporosis and the compound has the structure



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Claim 34 (currently amended): The method of claim 33 wherein

- (1) R^1 and R^4 are -OH, R^2 and R^3 are -H and R^9 is -CH₂-;
- (2) R^1 and R^4 are -OH, R^2 is -H, R^3 is -Br and R^9 is -CH₂-;
- (3) R^1 and R^4 are -OH, R^2 is -H, R^3 is -F and R^9 is -CH₂-;
- (4) R^1 , R^2 and R^4 are -OH, R^3 is -H and R^9 is -CH₂-;
- (5) R^1 , R^2 and R^4 are -OH, R^3 is -Br and R^9 is -CH₂-;
- (6) R^1 , R^2 and R^4 are -OH, R^3 is -F and R^9 is -CH₂-;
- (7) R^1 , R^3 and R^4 are -OH, R^2 is -H and R^9 is -CH₂-;
- (8) R^1 , R^2 , R^3 and R^4 are -OH and R^9 is -CH₂-;

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(9) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are $-H$ and R^9 is $-CH_2-$;

5 (10) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is $-H$, R^3 is $-Br$ and R^9 is $-CH_2-$;

(11) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is $-H$, R^3 is $-F$ and R^9 is $-CH_2-$;

10 (12) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is $-H$, R^3 is $-OH$ and R^9 is $-CH_2-$;

(13) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are $-OH$ and R^9 is $-CH_2-$;

(14) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is $-OH$, R^3 is $-H$, $-F$, $-Cl$ or $-Br$ and R^9 is $-CH_2-$;

20 (15) R^1 is $-H$, R^2 is $-OH$ or $=O$, R^3 is $-OH$, $-F$, $-Cl$ or $-Br$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and R^9 is $-CH_2-$;

(16) R^1 and R^2 are $-H$, R^3 is $-OH$ or $=O$, $-F$, $-Cl$ or $-Br$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and ~~R^9 is $-CH_2-$~~ ; and R^9 is $-CH_2-$;
25 or

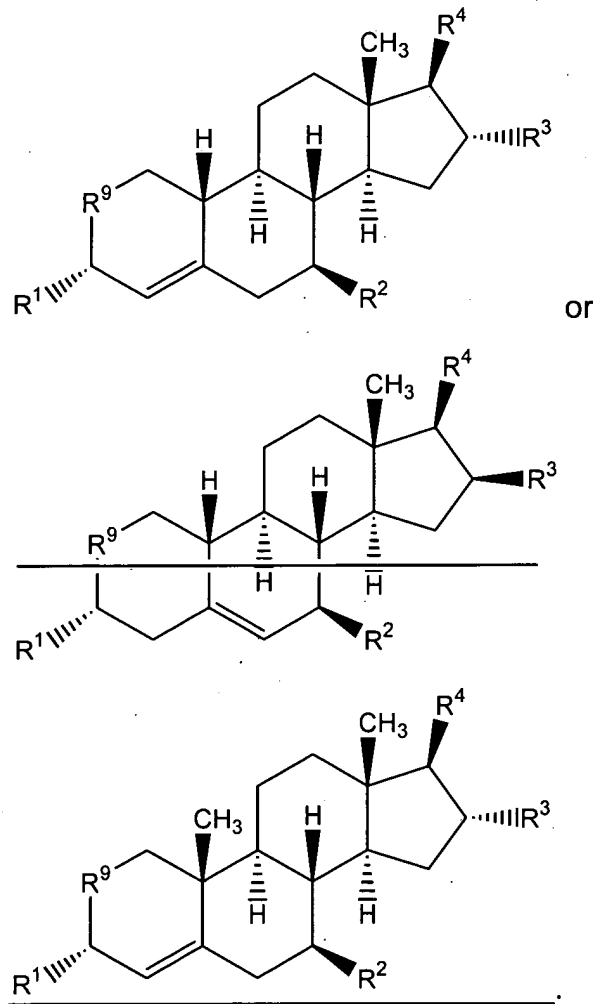
(17) R^1 is $-OH$, R^2 is $-OH$ or $=O$, R^3 is $-H$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and ~~R^9 is $-CH_2-$~~ ; and R^9 is $-CH_2-$.

(18) ~~any of (1) through (17) above wherein R^9 is $-O$ instead of $-CH_2-$~~ ;

30 or

(19) ~~any of (1) through (17) above wherein R^9 is $-NH$ instead of $-CH_2-$~~ .

Claim 35 (currently amended): The method of claim 32 wherein the compound has the structure



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Claim 36 (currently amended): The method of claim 35 wherein the subject has osteoporosis and the compound is 3 α ,17 β -dihydroxy-19-norandrost-4-ene, 3 α ,17 β -dihydroxy-19-norandrost-5-ene, 3 α ,17 β -dihydroxyandrost-4-ene, 3 α ,17 β -dihydroxyandrost-5-ene, 3 α ,16 α ,17 β -trihydroxy-19-norandrost-4-ene, 3 α ,16 α ,17 β -trihydroxy-19-norandrost-5-ene, 3 α ,16 α ,17 β -trihydroxyandrost-4-ene, 3 α ,16 α ,17 β -trihydroxyandrost-5-ene, 3 α ,7 β ,17 β -trihydroxy-19-norandrost-4-ene, 3 α ,7 β ,17 β -trihydroxy-19-norandrost-5-ene, 3 α ,7 β ,17 β -trihydroxyandrost-4-ene, 3 α ,7 β ,17 β -trihydroxyandrost-5-ene, 3 α ,17 β -dihydroxy-16 α -fluoro-19-

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norandrost-4-ene, ~~3 α ,17 β -dihydroxy-16 α -fluoro-19-norandrost-5-ene, 3 α ,17 β -~~
~~dihydroxy-16 α -fluoroandrost-4-ene, 3 α ,17 β -dihydroxy-16 α -fluoroandrost-5-ene,~~
~~3 α ,17 β -dihydroxy-16 α -bromo-19-norandrost-4-ene, 3 α ,17 β -dihydroxy-16 α -~~
~~bromo-19-norandrost-4-ene or 3 α ,17 β -dihydroxy-16 α -bromo-19-norandrost-5-~~
5 ~~ene, 3 α ,17 β -dihydroxy-16 α -bromoandrost-4-ene or 3 α ,17 β -dihydroxy-16 α -~~
~~bromoandrost-5-ene.~~

Claim 37 (previously presented): The method of claim 36 wherein the
compound is 3 α ,17 β -dihydroxy-19-norandrost-4-ene.

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